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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KOTINI, PAVITRA

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,826

Applicant(s)

HILL ET AL.

Examiner

Pavitra Kotini

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 13-22, and 34-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 23-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/14/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I and II in the reply filed on 8/15/06 is acknowledged. The traversal is on the ground(s) that separate subclassification does not make Group I different from Group II and does not cause serious burden on the examiner. This is not found persuasive because the USPTO classification system distinguishes inventions based not only on classes, but also subclasses. Hence, the fact that Group I and II are in the same class does not render the groups to have the same search. Rather, classification into different subclasses is basis for showing that there are different limitations in the two groups and therefore the two groups have acquired separate status in the art. As a result, the inventions of Group I and II will require a different field of search and will cause serious burden on the examiner. Although there may be some overlap in the search, the search nevertheless will be different in order to meet the different limitations of Group II.

Furthermore, Group I, which is drawn to a coupler device does not overlap in scope and are not obvious variants to the invention of Group II, which is drawn to a coupler holder and delivery device. In addition, the coupler (Group I) or the coupler holder and delivery device (Group II) can be separately used. For instance, the coupler holder and delivery device can be used to hold and deliver an entirely different object such as a screw or tubing. The requirement is still deemed proper and is therefore made FINAL.

Claim 13-22 & 35-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/15/2006.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-12 and 23-33 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 and 23-33 of copending Application No. 10/715441. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Both applications have verbatim language in the claims stated above.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by **Manzo et al** (WO 98/40036).

Regarding claim 1, Manzo discloses a coupler comprising: a saddle (20, fig.1); a channel (24, fig.1), wherein said channel comprises a first end having a substantially elliptical cross-section connected to said saddle (base of channel, fig.1 & 2) and a second end having a substantially circular cross-section (top of channel, fig.1 & 2); a tissue clamp positioned around said channel (14, fig.1 & 2); and a flange formed adjacent to said second end of said channel (16, fig. 2).

Regarding claim 6, Manzo discloses the cross-sectional area of said channel remains substantially constant as said channel transitions from said first end to said second end (lumen of channel 24, fig. 3).

Regarding claim 7, Manzo discloses the cross-sectional area of said channel (24, fig. 3) increases or decreases as said channel transitions from said first end to said second end (ramped surface 26, fig. 3; pg.6, lines 6-7).

Regarding claim 8, Manzo discloses a mating surface formed adjacent to said flange (above and below flange 16, fig. 2).

Claims 1-3, 5,6-8, 12, and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by **Carson et al** (US 2005/0192604).

Regarding claim 1, Carson discloses a coupler comprising: a saddle (14, fig.1A); a channel (18, fig. 1A), wherein said channel comprises a first end having a

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substantially elliptical cross-section connected to said saddle (connection of channel to lumen, fig. 3D; I, fig 5A) and a second end having a substantially circular cross-section (18, fig. 1A); a tissue clamp positioned around said channel (16, fig. 1A); and a flange formed adjacent to said second end of said channel (32, fig. 1A).

Regarding claim 2, 3, & 12, Carson discloses tissue clamp comprises a shape-memory alloy, and that shape memory alloy comprises a nickel titanium, also known as nitinol (para. 0079).

Regarding claim 5, Carson discloses the tissue clamp comprising a plurality of dimpled holes formed therethrough (fig. 9A, 9B).

Regarding claim 6, Carson discloses the cross-sectional area of said channel's inner surface to be substantially constant as said channel transitions from said first end to said second end (lumen of channel 18, fig. 3C).

Regarding claim 7, Carson discloses the cross-sectional area of said channel increases or decreases as said channel transitions from said first end to said second end (exterior of channel 18, fig, fig. 3C).

Regarding claim 8, Carson discloses a mating surface formed adjacent to said flange (in between flanges 34, fig. 3D).

Regarding claim 33, Carson discloses a channel comprising a first end of circular cross section (124, fig. 8) connected to the saddle (112, fig. 8) and a second end of substantially circular cross section (top of channel, fig. 8) adjacent to the flange (a reinforcing component 18, fig.8).

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manzo in view of Berreklouw (WO 00/24339). Manzo discloses the invention substantially as claimed above.

Regarding claim 4, Manzo teaches a tissue clamp, but does not expressly disclose teeth along the periphery of the clamp. Berreklouw teaches a tissue clamp (45, fig. 8) with teeth (26, fig. 8) along the perimeter of the tissue clamp. This arrangement has the apparent advantage of ensuring better connection between the tissue clamp and the vessel. Therefore, it would have been obvious to a person of ordinary skill in the art to modify the tissue clamp of Manzo to include teeth, as taught by Berreklouw to obtain the same advantage.

Regarding claim 9, Manzo discloses a tissue clamp, but fails to expressly teach a pair of legs on the tissue clamp. However, Berreklouw teaches another embodiment of a tissue clamp (115, fig. 5) with a pair of legs (117, fig. 5) which can be extended and positioned accordingly to another part of the anastomosis device (K, fig. 4) to create adequate clamping force. Therefore, it would have been obvious to a

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person of ordinary skill in the art to modify the tissue clamp of Manzo to include legs as taught by Berreklouw in order to have the tissue clamped adequately to the saddle.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carson as applied to claim 1 and further in view of Kavteladze et al (6814750). Carson discloses the claimed invention except that the material is made from a material having an austenitic temperature below 10 degrees Celsius. However, Kavteladze discloses that the transformation temperature of austenitic state nickel titanium alloy is below the normal temperature of a human body (col.10, lines 43-48), which would allow the material to exhibit relatively high tensile strength and be stable. Below ten degrees includes the range below body temperature, hence, since the tissue clamp disclosed by Carson is made from nickel titanium, the tissue clamp would also exhibit the property of having an austenitic transition temperature below 10 degrees Celsius. Therefore, it would be obvious to a person of ordinary skill in the art, at the time of the invention, that the nickel titanium tissue clamp disclosed by Carson can be modified as taught by Kavteladze to exhibit the same advantage stated above.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carson as applied to claim 1 and further in view of Boylan et al (US 6554848). Carson discloses the invention substantially as claimed above. Carson does not disclose that the material has an austenitic temperature equal to or greater than body temperature. Boylan, however, discloses making a device implantable within the body with a nickel titanium alloy having an austenitic phase above body temperature, or 37 degrees Celsius (claim 14), which would allow the material to exhibit relatively high tensile strength and be

stable. Therefore, it would have been obvious to a person of ordinary skill in the art, at the time of the invention, that the nickel titanium tissue clamp disclosed by Carson is modified as taught by Boylan to obtain the same advantage.

Claim 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al (US 2005/019264) in view of Akin et al (US 2002/0161383).

Regarding claim 23, Carson discloses a coupler having a saddle (14, fig.1A); a channel (18, fig. 1A), a tissue clamp (16, fig. 1A), and a flange (32, fig. 1A). Carson also discloses in fig. 21C that a combination of this coupler could be used (end of para. 0109) to create a conduit coupling device. So, referring to fig. 21C, since there are two couplers, then there would be two saddles, two channels, etc. where the coupler on the left can be referred to have the first saddle, channel, etc. and the coupler on the left could comprise of the second saddle, channel, etc. However, Carson does not expressly disclose a clamping ring to connect the two flanges of the two couplers.

Akin, however, teaches a securement ring (122, fig. 11B) for bringing together the flanges of two separate couplers (para. 0097). This arrangement has the apparent advantage of reinforcing the attachment of the two couplers to combat other internal forces. Therefore, it would have been obvious to a person of ordinary skill in the art to modify the conduit coupling arrangement of Carson to include a clamping ring as taught by Akin.

Claims 24, 25, 26, 27, 28, 29, 30, and 31 are the duplication of parts of claims 6,7,8, 2, 5, 3, 1, and 1 respectively. The exact replica of the device limitations claimed earlier is now being used in plurality. This duplication of limitations does not render any

unexpected result and therefore does not have patentable weight. Hence, the same rejection by Carson also holds of these claims. See MPEP 2144.04, section VI.

Regarding claim 32, Akin discloses that the first coupler or first saddle may be positioned at varying positions relative to said second coupler or second saddle (fig. 9-11B, which shown a side-to-side coupling device, or fig. 12A-B, 13, 14, and 15A-B, which shown an end-to-side coupling device). The first set of figures compared to the second set of figures shows different possible locations for the first coupler and saddle relative to the second coupler and saddle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M & W-F 9:00am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call
800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER

2/3/06.